

Check out the SPL Working Group WIKI @:  
<http://spl-work-group.wikispaces.com>

**Questions on SPL:**

ER/DL regulatory questions? Send to [edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov)

SPL technical questions? Send to [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov)

UNII or SRS questions? Send to [fda-srs@fda.hhs.gov](mailto:fda-srs@fda.hhs.gov)

*As of May16 , 2012: DailyMed has over 37,000 SPL loaded.*

**Notes:**

- **New Section header: Health Care Provider Letter Section (drug shortages)**
  - Companies have been offering for import drugs associated with US drugs in a shortage situation.
  - FDA has worked with some of these companies already to work out details, and will be issuing a Validation rule e-mail when this type of SPL file is going live.
  - Internal discussions: drug products offered for import as part of the drug shortage remediation should be listed.
  - These products are only to be imported on a temporary basis.
  - There can also be reimbursement issues – so FDA needed to add new terminology to address the situation of drugs import
  - Unapproved drug for use in drug shortage = new Marketing Category  
Validation rule will require the Dear HCP text in the first section.
  - At this time, these establishments do not need to be registered. There will be a requirement that there be establishment information, just not a check against already registered establishments
  - Labeler code request file will probably be required.
  - Dear Healthcare Provider letter needs to be included in the file as the first section of the SPL.
  - What about foreign language in the label? CBER, CDER and CVM have all been having discussions on how to handle the listings for this product.
  - Companies needing to list that didn't previously have Gateway accounts – the ESG group has agreed to expedite the establishment of accounts.
  - Market end date = likely to be the expiry date of the last lot.
  - Drug Shortages site for more general information:  
<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>

- <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm> - links to Dear Customer letters are throughout the table of current Drug Shortages.
- **Implementation of the validation procedure for the product-to-establishment data relationship for CDER-regulated drug products - July 1 , 2012**
- **Technical Q&A sessions begin May 21**  
for more information on registration, check this page: <http://spl-work-group.wikispaces.com/Training>
- **Establishment De-Registration [Howard]**  
Established as a document type to handle the situation where the registrant no longer has a requirement to list. Prior to this new term, a company would have to file an 'Out of Business' category.

**AOB:**

PERI: Global Labeling Process Design and Evaluation

**May 21, 2012 08:00am - May 22, 2012 05:00pm**

[https://netforum.avectra.com/eweb/DynamicPage.aspx?Site=PERI&WebCode=EventDetail&&vt\\_key=89c8dbab-b7d7-44d7-994d-2f38b2d34182&goback=.gde\\_4363942\\_member\\_116049910.gde\\_4363942\\_member\\_115363021](https://netforum.avectra.com/eweb/DynamicPage.aspx?Site=PERI&WebCode=EventDetail&&vt_key=89c8dbab-b7d7-44d7-994d-2f38b2d34182&goback=.gde_4363942_member_116049910.gde_4363942_member_115363021)

**Next meeting scheduled for May 30, 2012. (If we have agenda items)**